

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE: SUBOXONE (BUPRENORPHINE  
HYDROCHLORIDE AND NALOXONE)  
ANTITRUST LITIGATION

MDL No. 2445

This Document Relates To:

Master File No. 2:13-md-02445-MSG

*United Food and Commercial Workers Health  
and Welfare Fund of Northeastern  
Pennsylvania v. Reckitt Benckiser, Inc., et al.,  
No. 2:13-cv-03229-MSG (E.D. Pa.)*

*Meridian Health Plan Of Michigan, Inc., v.  
Reckitt Benckiser Group Plc, et al., No. 2:13-  
cv-01594-MSG (E.D. Pa.)*

*Painters District Council No. 30 Health and  
Welfare Fund v. Reckitt Benckiser, Inc., et al.,  
No. 2:13-cv-03450-MSG (E.D. Pa.)*

*A.F. of L. - A.G.C. Building Trades Welfare  
Plan v. Reckitt Benckiser, Inc., et al., No. 2:13-  
cv-03545-MSG (E.D. Pa.)*

*Michigan Regional Council of  
Carpenters Employee Benefits Fund, v. Reckitt  
Benckiser Group Inc., et al., No. 2:13-cv-  
01808-MSG (E.D. Pa.)*

*I.B.E.W. 292 Health Care Plan v. Reckitt  
Benckiser, Inc., et al., No. 2:13-cv-02454-MSG  
(E.D. Pa.)*

*Teamsters Health Services and Insurance Plan  
Local 404 v. Reckitt Benckiser, Inc., et al., No.  
2:13-cv-03451-MSG (E.D. Pa.)*

*Construction & General Laborers' Local 190  
Welfare Fund v. Reckitt Benckiser, Inc., et al.,  
No. 2:13-cv-04430-MSG (E.D. Pa.)*

*New York Hotel Trades Council & Hotel Assoc.  
of New York City, Inc. Health Benefits Fund v.  
Reckitt Benckiser, Inc., et al.*, No. 2:13-cv-  
03381-MSG (E.D. Pa.)

**END PAYOR PLAINTIFFS' CONSOLIDATED AMENDED CLASS ACTION  
COMPLAINT**

End Payor Plaintiffs ("Plaintiffs") bring this class action on behalf of themselves and all others similarly situated against Reckitt Benckiser Inc., Reckitt Benckiser LLC, Reckitt Benckiser Pharmaceutical, Inc., Reckitt Benckiser Healthcare (UK) Ltd., and Reckitt Benckiser Group plc (collectively, "Reckitt" or "Defendants"), and allege as follows based on: (a) personal knowledge; (b) the investigation of counsel; and (c) information and belief.

**I. NATURE OF THE ACTION**

1. This is a civil antitrust action seeking damages arising out of Reckitt's unlawful impairment of competition in the market for co-formulated buprenorphine hydrochloride and naloxone hydrochloride dihydrate ("Suboxone" or "Co-Formulated Buprenorphine/Naloxone"), which Reckitt sells under the brand-name Suboxone. As alleged below, Reckitt used various anticompetitive acts and practices as part of an overall scheme to improperly maintain and extend its monopoly power in the market for Suboxone, to the detriment of Plaintiffs and the class of end-payors they seek to represent (as defined below), causing them to pay overcharges.

2. Suboxone, with annual U.S. sales of over \$1 billion, accounts for approximately 20% of Reckitt's profits. Reckitt knew, however, that its unpatented Suboxone tablet product was vulnerable to a rapid, near-complete loss of sales upon the entry into the market of less expensive, generic Suboxone tablets once its regulatory exclusivity expired on October 8, 2009. As Reckitt repeatedly warned its shareholders, generic competition to Suboxone was, in

Reckitt's words, a question of "when not if." Recognizing the dire threat that generic competition posed to its bottom line, Reckitt engaged in a multi-step scheme to delay and impair generic competition to Suboxone.

3. As explained in more detail below, Reckitt's overall scheme consisted of a series of anticompetitive tactics:

**A. Product Hopping** – In order to prevent the vast majority of the Suboxone prescription base from being automatically substituted with less expensive generic versions, Reckitt developed and commercially launched Suboxone in sublingual film form before the Food and Drug Administration ("FDA") approved generic Suboxone tablets. The film is no more safe or effective than the tablet form and is actually inferior to the tablet in many ways. The only "benefit" of the new dosage form was to Reckitt, not to consumers; because Suboxone film would not be "AB-rated" to Suboxone tablets, pharmacists could not legally substitute less-expensive generic Suboxone tablets when presented with a prescription for Suboxone film. The film version, unlike the tablet, is patent-protected until 2023 and so does not face imminent generic competition. Once the FDA approved Reckitt's Suboxone film product, Reckitt employed its army of sales force detailers to aggressively destroy demand for the unpatented tablet product and switch prescriptions to its patented film product by falsely disparaging and artificially raising the price of tablets relative to the film. Then, once the entry of generic Suboxone tablets was imminent, Reckitt announced to the public, and marketed to doctors, that Reckitt had decided to withdraw its own tablets from the market due to a purported significant safety concern with tablets. In fact, there was no legitimate safety concern, as the FDA ultimately found. Instead, Reckitt announced the withdrawal of the tablets not due to any

real safety concern, but solely as part of a successful effort to scare doctors into switching prescriptions from the tablets to the film. As a result, once generic Suboxone tablets finally launched in February 2013, the market for tablets had all but been eliminated by Reckitt's coercive product-switching tactics.

**B. Sabotaging FDA Approval Of Generic Suboxone Tablets** – It is well known in the pharmaceutical industry that a product-hopping scheme such as Reckitt's will not succeed to the extent that the brand manufacturer has failed to switch prescriptions to the new branded product before the generic versions of the original product enter the market. So in 2011 and 2012 Reckitt saw that it had a big problem—generic Suboxone tablets were expected to enter the market by May 2012, and by that time Reckitt would have converted only about 50% of its Suboxone sales from the tablet to the film. This left more than \$500 million of Reckitt's annual Suboxone revenue exposed to immediate loss to generic competition. Reckitt therefore bought itself more time to destroy demand for Suboxone tablets and switch the market to Suboxone film by sabotaging the process by which it and the generic manufacturers were required to finalize and submit an FDA-mandated shared risk mitigation plan for Suboxone tablets. The approval of this shared risk mitigation plan was at that time the only thing preventing at least two generic Suboxone tablet products from receiving final FDA approval. Rather than cooperate with the generic manufacturers, as it had been ordered to do by the FDA, Reckitt used baseless delay tactics to prevent, for as long as it could, FDA approval of generic Suboxone tablets. And Reckitt's stalling tactics did in fact substantially delay FDA approval of generic Suboxone tablets.

**C. Sham Citizen's Petition** – Using the information that it gained by feigning cooperation in the shared risk mitigation process, Reckitt learned that the FDA would likely grant final approval to several generic tablets in the Fall of 2012. By that time, Reckitt had still converted only about 70% of its unit sales from the tablet to the film, thus leaving more than \$300 million in annual revenue exposed to generic competition. Therefore, with FDA approval of generic versions of Suboxone tablets imminent, Reckitt filed an objectively baseless, sham Citizen Petition with the FDA. The baseless petition argued, among other things, that Reckitt had suddenly discovered, after ten years on the market with its own tablet product, a safety issue so severe as to require that the tablets be withdrawn from the market within the next six months. Reckitt filed the sham petition on September 25, 2012, even though it had represented to FDA just a few weeks earlier that the risk mitigation strategies that Reckitt already had in place for the tablets were successful and did not require any changes. Reckitt knew that the mere filing of the Citizen Petition would substantially delay FDA approval of generic Suboxone tablets, and Reckitt filed the meritless petition solely to cause this delay. FDA denied the Citizen Petition on February 22, 2013, but the Petition accomplished what Reckitt intended, because the mere pendency of the meritless petition succeeded in delaying the FDA's approval of generic Suboxone tablets. FDA did not approve the generic tablets until February 22, 2013, the same day that FDA issued its stinging denial of Reckitt's Citizen Petition. By then, however, Reckitt had finally succeeded in converting the vast majority of Suboxone sales from the tablet to the film.

4. Absent Reckitt's anticompetitive scheme, generic Suboxone tablets would have entered the market no later than December 22, 2011. And when those generics entered, they

would have been automatically substitutable for 100% of the units of branded Suboxone—all \$1.025 billion of Reckitt’s annual sales of Suboxone at that time would have been in tablet form. Within nine months, generics would have captured almost all of those sales at vastly lower prices, delivering savings of more than \$650 million annually to Suboxone purchasers. As a result of Reckitt’s anticompetitive scheme, however, when generic Suboxone tablets finally entered the market in February 2013, Reckitt had converted some 85% of the unit sales from tablets to the non-substitutable film. Consequently, less than \$160 million of Reckitt’s annual sales of Suboxone were in tablet form and thus available for automatic generic substitution. Reckitt’s anticompetitive scheme has robbed consumers of the benefits of generic competition—to the tune of at least some \$500 million annually.

## **II. DETAILED FACTS REGARDING RECKITT’S ANTICOMPETITIVE SCHEME**

5. Suboxone (Co-Formulated Buprenorphine/Naloxone) is a unique combination drug product composed of two active pharmaceutical ingredients used together as opioid replacement therapy for the maintenance treatment of opioid dependence (*e.g.*, heroin addiction). The buprenorphine supplies the patient with a maintenance dose of a semi-synthetic opioid, absorbed through the oral mucosa. The naloxone, in theory at least, serves to prevent the patient from abusing the buprenorphine, by blocking the action of the buprenorphine and thereby precipitating immediate withdrawal symptoms if the buprenorphine is, for instance, ground, put into solution, and injected intravenously. The naloxone in Suboxone will not have such a blocking effect, however, if the buprenorphine is used sublingually as directed, because naloxone is poorly absorbed through the oral mucosa.

6. When Reckitt introduced Suboxone tablets, buprenorphine and naloxone were no longer innovative drugs; in fact, they were quite old. Naloxone was first approved by the FDA

in the 1970s. Buprenorphine was first approved by the FDA in 1982 as an injectable analgesic (pain) drug, first marketed by a predecessor to Reckitt. Much of the research to investigate buprenorphine's utility in opioid dependence was paid for by United States taxpayers, through grants to Reckitt from the National Institutes of Health. Thus, when it introduced Suboxone sublingual tablets in 2002, Reckitt knew that neither Suboxone's components nor their use in opioid replacement therapy had any patent protection. In fact, in its application to the FDA for approval of Suboxone, Reckitt stated that it "has no knowledge of any patent that claims the drugs or any methods of using the drugs that are the subject of this application."

7. Reckitt did have some protection against generic competition to Suboxone, however. When Suboxone was approved, the FDA granted Reckitt a 7-year period of regulatory exclusivity, categorizing Suboxone as an "orphan drug." *See* 21 U.S.C. § 360aa-dd. During that period of exclusivity, Reckitt marketed Suboxone tablets free from competition from generic Co-Formulated Buprenorphine/Naloxone, garnering United States sales of over \$1 billion per year, far above the commercial potential that typically entitles a drug company to orphan drug exclusivity, and contrary to Reckitt's representation in its successful application for orphan drug exclusivity that there was no reasonable expectation that Reckitt could recover the costs associated with making and developing the drug (much of which, as stated above, had in any event been borne by United States taxpayers).

8. Reckitt's 7-year orphan drug exclusivity for Suboxone tablets was set to expire on October 8, 2009, and Reckitt knew that less-expensive generic competition could arrive with the end of the exclusivity period. In fact, multiple generic manufacturers have sought FDA approval to market generic versions of Suboxone tablets.

9. The prospect of generic competition was alarming to Reckitt because Suboxone (despite Reckitt's assurance to the FDA that Reckitt had no reasonable expectation it would even recover its costs on the drug) was extremely profitable to Reckitt and formed a substantial portion of Reckitt's revenue and profits. Reckitt knew that generic competition posed a substantial threat to those profits. Since generic products are generally priced significantly below the price of the brand-name drug, they typically take the vast majority of the brand's sales shortly after their introduction into the marketplace. Reckitt projected that it would lose 80% of its Suboxone tablet sales to generic Suboxone in the first year generic tablets were on the market, with further revenue and profit erosion thereafter.

10. Not satisfied with the government-bestowed exclusivity for a drug developed and reimbursed in significant part by U.S. taxpayer money, Reckitt concocted a multifaceted anticompetitive scheme, executed over the course of several years, to maintain and extend its monopoly power over Co-Formulated Buprenorphine/Naloxone, by illegally preventing generic manufacturers from effectively competing with Suboxone. Reckitt executed its scheme through a purposeful and planned manipulation of the complex distribution and regulatory approval systems for pharmaceutical products in the United States. The scheme was comprised of number of steps.

**A. Step One: Reckitt Develops Suboxone Film**

11. In order to be approved by FDA as AB-rated to a particular branded product, and thereby become automatically substitutable for a branded product at the pharmacy counter, a generic product must be, among other things, "pharmaceutically equivalent" (same dosage form and strength) and "bioequivalent" (exhibiting the same drug absorption characteristics) as the branded product.



12. FDA regulations, which are concerned only with safety and effectiveness and not with effects on competition, permit brand manufacturers to seek FDA approval to modify the dosage form of their existing products. An unscrupulous brand manufacturer that anticipates the onset of generic competition to its drug can modify the dosage form of its product from, say, A to A<sub>1</sub>, for no reason other than to impair generic competition to A. Before the generic manufacturer receives FDA approval for the generic version of A and enters the market, the brand manufacturer might get approval for A<sub>1</sub> and use various tactics to cause physicians to write prescriptions only for A<sub>1</sub> instead of A. The brand manufacturer's modification of A to A<sub>1</sub> may thereafter cause the manufacturer of the generic version of A to garner few or no sales, because its product is not substitutable for A<sub>1</sub>.

13. This anticompetitive tactic, known in the industry as "product hopping," destroys the automatic substitutability of generic drugs for their branded counterparts. And automatic substitutability is generic manufacturers' only commercially viable means of distributing their products. Generic manufacturers cannot profitably market their products to doctors through journal advertising, personal promotion ("detailing") to doctors, and the like, the way that brand manufacturers do. That type of product promotion is very expensive and generally is not economically feasible once generics are available. Once generics of a product are or will soon be available, no manufacturer—whether brand or generic—can profitably promote the product to doctors. Even if the promotion is successful and the doctor writes the prescription for that product, a pharmacist could easily substitute some other generic version of the product. This post-generic-entry automatic substitutability usually makes active promotion of the product by anyone—brand and generic manufacturers alike—economically infeasible. Unable to distribute

their products through promotion to doctors, generic manufacturers instead get distribution by competing on price for sales to pharmacies.

14. The very thing that makes generic drugs attractive—automatic substitutability at the pharmacy counter—generally makes automatic substitution (and consequent low prices) the *only* commercially viable means for generic manufacturers to distribute their products. The whole point of Reckitt’s product hop scheme was to destroy automatic substitutability and to thus substantially impair the generic competitors’ only commercially viable means of competing.

15. In order to destroy automatic substitutability, in July of 2007—more than two years before its orphan drug exclusivity expired—Reckitt announced to the FDA that it planned to apply to market a sublingual film version of Suboxone. Reckitt filed its application on October 21, 2008.

16. Reckitt’s product hop did not go as smoothly as Reckitt had hoped—it had significant difficulty getting Suboxone film approved by the FDA. The FDA rejected Reckitt’s application to market a film formulation of Suboxone on August 21, 2009—less than two months before Reckitt’s exclusivity on its tablet formulation was set to expire—because the FDA was concerned that the film formulation could be abused by patients or others, or could result in accidental exposure to children. Ultimately, after Reckitt submitted a Risk Evaluation and Mitigation Strategy (“REMS”) to address these issues, the FDA approved Reckitt’s application to market the film formulation on August 30, 2010. Reckitt began marketing Suboxone film shortly thereafter, using a host of anticompetitive tactics (addressed in detail below) to cause doctors to switch prescriptions and prescribing habits from Suboxone tablets to the non-substitutable Suboxone film.

**B. Suboxone Film Is Inferior to Suboxone Tablets**

17. The new film formulation offered no medical or clinical benefits over the existing tablets. Medically speaking, the film was equivalent to the tablets. Until August 2012 its dosage strengths were the same as the tablets. In fact, Reckitt obtained FDA approval of the film version of Suboxone based almost entirely on previous studies that it used to establish the safety and efficacy of the tablets. Reckitt performed no efficacy studies on Suboxone film itself. Reckitt simply showed that the film version had sufficiently equivalent bioavailability compared with the tablet version. Reckitt itself told the FDA that any differences between the film and the tablet were “clinically insignificant.”

18. But in many respects the film formulation had numerous drawbacks compared to the tablets. Naloxone bioavailability with the film version was increased relative to the tablet version. This increased the risk of unwanted opioid withdrawal symptoms—the very condition Suboxone is designed to treat—and decreased the likelihood of successful induction and stabilization of patients taking the film. The new film formulation was also easier to dissolve and inject than the tablet formulation, defeating one of Suboxone’s major “virtues”—low abuse potential.

19. The new film formulation was also easier to conceal than the tablet version, and thus more susceptible to diversion. For example, because the Suboxone film strips are flat, they are easily placed under stamps, in bindings of books and hems of clothing and are smuggled into jails and prisons. Reckitt learned before the FDA approved Suboxone film that almost 6,000 strips (46% of those dispensed to study patients) were “missing” after the limited clinical studies Reckitt performed to support FDA approval.

20. Nor did patients prefer Suboxone film to Suboxone tablets; they preferred the tablets by a wide margin. The film formulation was more irritating than the tablet to a patient's oral mucosa. Moreover, the taste of the film was too strong, the film gummed up on patients' fingers when handled, the film strips were prone to blowing away in the wind when opened outdoors, the film was harder to divide into partial doses, and the wrappers were hard to dispose of at work without co-workers finding out that patients were taking Suboxone.

21. Due to all of these significant drawbacks, Reckitt does not market Suboxone in a film format *anywhere else in the world*. (Reckitt has approval to sell Suboxone in more than 30 other countries).

22. Reckitt reformulated Suboxone from tablets to film in the United States solely because the different dosage form prevented the FDA from giving generic Suboxone tablets the "AB-rating" that would make them automatically substitutable for branded Suboxone film. Pharmacists would not and could not legally substitute less-expensive generic Suboxone tablets when presented with a prescription for Suboxone film. Destroying automatic substitutability, and thus substantially impairing generic manufacturers' only commercially viable means of competing, was Reckitt's sole purpose in reformulating Suboxone from tablets to film.

23. The fact that Suboxone film was inferior to Suboxone tablets caused Reckitt very substantial public relations and commercial problems. Reckitt needed to somehow justify the product switch to the public and to doctors.

24. Reckitt therefore concocted the idea that the Suboxone film product was safer than Suboxone tablets for children who are accidentally exposed to the product. As alleged in detail below, Suboxone film itself is far less safe for children than are Suboxone tablets. So Reckitt hit upon the idea of selling Suboxone film in single-serving packets (so-called "unit-

dose” packaging) and asserting that this packaging made the product safer than the tablets, which Reckitt sold in the United States in child-resistant bottles that hold multiple tablets.

25. In fact, Reckitt’s “child safety” rationale was a complete fabrication and pretext. Reckitt’s sole reason for reformulating the product from tablets to film was to impair generic competition. And the unit-dose packaging brought no added measure of safety.

26. First, if Reckitt really believed that unit-dose packaging was necessary to protect children from accidental exposure to Suboxone, Reckitt would have sold its Suboxone tablets in unit dose packages. Reckitt knew since at least 2004 that some children were accidentally exposed to Suboxone tablets in the United States. Yet Reckitt continued to sell Suboxone tablets in multi-unit bottles, rather than unit-dose packages, from that time through March 2013. Reckitt’s epiphany that unit-dose packages are safer occurred only when and to the extent that this new knowledge was useful to Reckitt in impairing generic competition.

27. Second, Reckitt has admitted to the FDA that, during the time that Reckitt was busy reformulating the product from tablets to film, Reckitt knew that it was feasible for it to market the tablets in unit-dose packages. Despite this feasibility, and despite Reckitt’s knowledge of a potential problem with accidental exposure of children to Suboxone, Reckitt continued to sell hundreds of millions of dollars of Suboxone tablets in the United States every year.

28. Third, Reckitt in fact sold Suboxone tablets in unit-dose packages throughout much of the rest of the developed world. Reckitt gained approval to sell unit-dose-packaged Suboxone tablets in the European Union in 2006 and in Canada in 2007. The tablets that Reckitt sells in the European Union and Canada have the same formulation, in all material respects, as the formulation that Reckitt sold in the United States. If Reckitt genuinely believed that unit-

dose packaging was necessary to prevent accidental exposure to children, nothing stopped Reckitt from seeking similar approval for that packaging in the United States.

29. Fourth, as discussed in greater detail below, Reckitt spent six months ostensibly coordinating with generic manufacturers to prepare a joint plan to ensure the safe distribution of Suboxone. At no time during those extensive meetings and discussions did Reckitt ever assert or suggest that distributing Suboxone tablets in multi-unit child-resistant bottles was unsafe.

30. Fifth, until FDA approval of generic Suboxone tablets was imminent, Reckitt never told or suggested to the FDA that tablets in multi-unit bottles presented an undue safety concern for children. Instead, in June 2009 Reckitt told the FDA that Reckitt had worked with state and federal agencies, and with medical societies, to assure responsible distribution of Suboxone tablets “through a qualified and monitored distribution system designed to assure safe use” of those tablets. Citizen Petition No. 2009-P-0289, at 2-3. After the FDA approved the REMS for the tablets in 2011, Reckitt proposed no further revisions to it in order to address any alleged safety problems with respect to accidental exposures to children. In a REMS document that Reckitt submitted to FDA in connection with Suboxone tablets, Reckitt asserted that the existing REMS would “assure safe use” of Suboxone tablets. REMS submission to FDA dated December 22, 2011, at 1. As late as August 2012 Reckitt officially reported to the FDA that distribution of its own tablets in bottles, pursuant to the REMS then in effect (see below for further details) was safe and required no changes.

31. Sixth, Reckitt knew that merely changing its packaging from a child-resistant multi-unit bottle to unit-dose packaging would not prevent the FDA from approving generic Suboxone tablets, sold in child-resistant multi-unit bottles, as “AB-rated” and thus automatically substitutable for Reckitt’s unit-dosed tablets. Upon information and belief, Reckitt concluded

(correctly) that a change to unit-dose packaging would not cause the FDA to deny an AB rating to generic Suboxone tablets in bottles. Since there was no safety reason and no generic-impairment reason to market its Suboxone tablets in unit dose packages in the United States, Reckitt did not do so. Instead, Reckitt concentrated its product-development efforts on a change that *would* cause the FDA to deny an AB rating to the generics—the change in dosage form from tablets to film. Reckitt then added the unit-dose packaging to the film entirely as a safety pretext.

32. Seventh, the data in a study commissioned by Reckitt show that in fact unit dose packaging does not prevent accidental exposure of children to Suboxone. In instances in which it is possible to tell whether the exposure was to single, partial, or multiple doses of Suboxone, exposures to single or partial doses predominated. This data was then confirmed by the FDA, which studied 131 instances in which it was possible to tell whether the child had been exposed to single, partial, or multiple doses. Only 19 of those 131 (14.5%) exposures involved multiple doses.

33. Eighth, the data showing that most accidental exposures are of single or partial doses further highlights the pretextual nature of Reckitt's alleged safety concern. At all relevant times Reckitt knew that unit dose packaging may be substantially less effective than multi-unit bottles in protecting children from the far more predominant exposures to single or partial doses. Unlike with a child-resistant bottle, once a unit-dose package is opened there is no safe place to put the unused single or partial dose. This is a particular problem with Suboxone because Reckitt sold the tablets in only 2mg and 8mg dosages. A typical Suboxone regimen will start the patient on the 8mg dose, then scale the dosage down in 2mg increments every month or so. Thus, patients must break the 8mg tablet or film apart in order to get the 6mg and 4mg dosages.

Unit dose packaging leaves the patient with no secure place to put these unused portions, and, as noted above, it is these partial dosages, together with single dosages, that constitute the vast majority of accidental exposures for children. For these reasons, among others, the FDA specifically concluded that “we do not agree that the packaging for buprenorphine HCl and naloxone HCl sublingual film provides meaningful incremental protection against pediatric exposure.” Suboxone sublingual film, ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS, page 27,

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/022410Orig1s000AdminCorres.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022410Orig1s000AdminCorres.pdf).

34. Ninth, Reckitt’s alleged safety concerns are further shown to be pretextual because Suboxone film itself—regardless of the packaging—is substantially more dangerous for children than are the tablets. The new film formulation was more dangerous for any children who became accidentally exposed to Suboxone. The film dissolves rapidly, and thus children who accidentally place Suboxone film in their mouths tend to absorb the buprenorphine quickly and completely. Moreover, children have a hard time spitting out the film. Upon introduction into the mouth, Suboxone film turns into a gel within approximately 30 seconds, and erodes completely over the course of 3 minutes, releasing all the buprenorphine. In contrast, Suboxone tablets may take up to 10 minutes to dissolve, and children often spit them out, terminating their exposure to buprenorphine. Moreover, when children swallow tablets, the buprenorphine is absorbed to a far lesser extent compared with film.

35. Tenth, Reckitt repeatedly and expressly admitted that its true purpose in reformulating Suboxone and its packaging was to protect Reckitt’s Suboxone long-term profits by delaying and impairing generic competition. Thwarting generics, not protecting children, was Reckitt’s real goal. For example:



- Reckitt's 2007 Annual Report states that the revenue and income of the Suboxone business "may not be sustained going forward unless replaced with new . . . forms on which [Reckitt] is actively working."
- Reckitt's 2008 Annual Report states that it "continues to search for ways to offset the impact of the loss of exclusivity in the USA at the end of September [sic] 2009, up to 80% of the revenues and profits of that business might be lost to generic competition in 2010, with the possibility of further erosion thereafter."
- Reckitt's 2010 Annual Report states: "[I]n the event of generic competition to the Suboxone tablet, the Group expects that the Suboxone sublingual film will help to mitigate the impact thereof."
- Reckitt's 2010 Annual Report also states: "It is well known that by far the largest part of the Pharmaceuticals business, the Suboxone tablets in the USA, can become subject to generic competition at any time. To mitigate the potential impact of this, in August 2010 we launched a patent-protected . . . Suboxone film."
- Similarly, Reckitt's 2011 Annual Report states: Reckitt "has developed a new and patented sublingual film delivery method for this product which partially mitigates the risk exposure from the expected generic variant entry against tablets."

**C. Reckitt's Product Hop Made Economic Sense for Reckitt Only Because the Scheme Impaired Generic Competition.**

36. Reckitt's product hop from Suboxone tablets to film would have made no economic sense for Reckitt if the scheme did not have the intended effect of substantially impairing generic competition. The scheme caused Reckitt to incur substantial expense, but Reckitt expected Suboxone film to deliver no new sales or profits except those that Reckitt made

by impairing generic competition. Thus, the product hop's entire economic value to Reckitt came from impairing generic competition. Reckitt's sole motive was to substantially impair competition.

37. If the new Suboxone film represented a real improvement valued by consumers, Reckitt would have projected that the new product would garner more sales and/or a higher price than Reckitt had obtained from Suboxone tablets. Instead, Reckitt accurately projected exactly the opposite. Reckitt projected that it would make far fewer unit sales of Suboxone film—as much as 30% fewer—than it had of Suboxone tablets, and at a lower price.

38. Reckitt also incurred substantial additional costs to develop and manufacture Suboxone film and switch prescriptions from the tablets to the film. Reckitt incurred the significant costs of developing the film product and gaining FDA approval to market it. And Reckitt has to pay a substantial royalty to a third-party manufacturer that supplies the film technology to Reckitt. Moreover, Suboxone film is more difficult and costly than the tablets for Reckitt to manufacture. Reckitt also paid tens or hundreds of millions of dollars more for its sales force to get doctors to prescribe the film rather than the tablets. These factors caused Reckitt's North American business to experience substantially reduced profit margins and net revenue in 2011 and 2012.

39. But none of that mattered to Reckitt because it was willing to sacrifice short-term profits in order to destroy the market for Suboxone tablets. Reckitt's long-term gain came not from new sales or higher prices as a reward for a valuable innovation—there were no such new sales or increased prices because there was no valuable innovation. Instead, Reckitt's investments in product development, additional marketing, acquiring the film technology, and

the like represented an investment solely in impairing generic competition. *All* of Reckitt's gains from these costs came *solely* by means of impairing generic competition.

40. In sum, Reckitt's product hop would not have made economic sense absent its intended effect of substantially impairing generic competition; conversely, the product hop made economic sense for Reckitt solely because the scheme did have the intended effect of impairing generic competition. Reckitt itself made this point perfectly clear in its 2010 "Annual Business Review" for its shareholders: "As [Reckitt] is rapidly converting Suboxone tablets to the sublingual film, there is a short-term dilutive impact on net revenue and operating profit; however, this conversion much better protects the medium and long-term earnings stream from the Suboxone franchise in the US. Hence, in the event of generic competition to the tablet, [Reckitt] expects that the Suboxone sublingual film will help to mitigate the impact thereof."

#### **D. Step Two: Reckitt Destroys the Market for Suboxone Tablets**

41. After the FDA approved the film version of Suboxone, Reckitt took affirmative (and costly) steps to destroy the market for Suboxone tablets and simultaneously coerce physicians to prescribe, and patients to take, Suboxone film.

42. Reckitt used its relative prices of Suboxone tablets and Suboxone film to drive patients to the tablets. Reckitt significantly raised the price of Suboxone tablets, while leaving the price of Suboxone film level, thus creating an artificial price difference designed to steer patients away from the tablets to the film. For example, in July 2012 Reckitt charged an average price of \$140.00 for a 30-count bottle of the 2mg tablets, and \$252.00 for the 8mg tablets. In September 2012 Reckitt implemented a whopping 15% price increase on the tablets, to \$161.70 for the 2mg tablets and \$289.80 for the 8mg tablets. But Reckitt left the price of Suboxone film steady at \$117.85 for a 30-count carton of the 2mg films and \$211.15 for the 8mg

films. Including the effects of previous price hikes on the tablets, this created a total 27% difference in prices between the tablets and the film. Of course, the “savings” to consumers from the nominally lower prices on the branded film compared to the branded tablets was entirely an illusion. Absent Reckitt’s anticompetitive scheme, consumers could have bought generic Suboxone tablets at a 70%–90% discount to the branded tablets.

43. Reckitt reinforced its artificial price differences with misrepresentations to doctors and other industry participants. Reckitt directed its sales force to falsely disparage Suboxone tablets to doctors and payers. This disparagement included falsely stating to doctors and payers that Suboxone tablets presented a greater risk of exposure to children than did Suboxone film. As noted in detail above, Reckitt’s claims of superior safety for Suboxone film were entirely bogus.

44. Reckitt also directed its sales force to tell doctors that the film was more difficult than the tablets for patients or others to abuse by crushing and then ingesting in order to “get high.” This, too, was a complete falsehood. As alleged above, Suboxone film is far easier than the tablets for patients or others to dissolve and inappropriately inject or otherwise ingest. The truth is exactly the opposite of the message that Reckitt incessantly broadcast to doctors and other industry participants. The film strips, not the tablets, are more prone to abuse.

45. In September 2012, Reckitt issued a press release falsely advising the public and doctors that Reckitt intended to withdraw the tablets from the market within the next six months due to the “pediatric exposure safety issue.” Reckitt instructed its sales force to deliver the same fraudulent message to doctors and other industry participants, asserting that Reckitt would imminently withdraw the tablets from the market due to child-safety concerns. In fact, the FDA determined that there was no evidence that the tablets “were, or should have been, withdrawn

from sale for reasons of safety.” *Determination that SUBOXONE (Buprenorphine Hydrochloride and Naloxone Hydrochloride) Sublingual Tablets, 2 Milligrams/0.5 Milligrams and 8 Milligrams/2 Milligrams, Were Not Withdrawn From Sale For Reasons of Safety or Effectiveness*, 78 FR 34108 (June 6, 2013). Reckitt’s real and sole purpose in announcing the imminent withdrawal of the tablets from the market was to further coerce doctors to switch their prescriptions and prescribing habits from the tablets to the film.

46. By the time generic manufacturers began selling generic Suboxone tablets in late February 2013, Reckitt’s anticompetitive tactics had almost completely destroyed the prescription base for Suboxone tablets. Some 85% of Suboxone prescriptions were already being written for the film version of Suboxone.

47. Reckitt took each and every one of these steps with a single goal in mind: to manipulate the market by destroying the prescription base for Suboxone tablets before generic tablets entered the marketplace, thereby preventing generic Suboxone tablets from effectively competing through the most efficient means available—automatic generic substitution at the pharmacy counter.

#### **E. Step Three: Reckitt Holds ANDA Approvals Hostage**

48. Delaying FDA approval of the generic Suboxone tablets was critical to Reckitt’s product hop scheme. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. For example, one brand manufacturer estimated that it would make ten times more sales of its branded follow-on product if it beat generic versions of the original product onto the market. In a detailed inquiry into the pharmaceutical industry, the European Commission concluded that “it

is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity.” European Commission, Final Report, p. 356 (8 July 2009), available at [http://www.europa-nu.nl/id/vi6wcj7amsx3/pharmaceutical\\_sector\\_inquiry\\_fianl?start-006-00c=10](http://www.europa-nu.nl/id/vi6wcj7amsx3/pharmaceutical_sector_inquiry_fianl?start-006-00c=10). Industry analysts in the United States have reached the same conclusion, warning brand manufacturers that it is essential that they switch patients to the new formulation before the generic enters.

49. It is equally well known that, if the reformulated brand product does beat the generic original product onto the market, generics can *never* regain most (or all) of those lost sales. Having switched their prescribing habits from the original to the reformulated product—and having switched specific patients’ medications from the original to the reformulated product—most doctors will not switch their prescribing habits or their patients back to the original product after the generic is available. And pharmacists are unable to effect the switch through the efficient mechanism of automatic substitution because the dosage form is different. Thus, in most instances, the generic’s opportunity to compete for those sales is gone forever.

50. In order to give itself more time to switch the market from Suboxone tablets to film, Reckitt used additional anticompetitive tactics to delay would-be generic Suboxone tablet sellers from obtaining FDA approval of their Abbreviated New Drug Applications (“ANDAs”) for generic Suboxone tablets. Reckitt did this by sabotaging the process by which it and the generic manufacturers were required to finalize and submit to the FDA a shared REMS for Suboxone tablets. On January 6, 2012, the FDA advised Reckitt and the generic manufacturers of the need for a joint REMS. FDA approval of the joint REMS was the final regulatory hurdle before FDA would approve generic Suboxone tablets. The FDA demanded compliance by May 6, 2012.

51. The FDA required the shared REMS, but it did not contemplate that Reckitt would use the requirement of a shared REMS to delay FDA approval of the generics. In fact, given that it had just approved Reckitt's Suboxone tablet REMS in December 2011, the FDA contemplated rapid development of a shared REMS. The FDA underestimated Reckitt's willingness to blatantly violate the statute regulating the REMS process in order to delay generic competition. That statute provides that "No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection [Risk Evaluation and Mitigation Strategies, *i.e.*, REMS] to block or delay approval of an application under section 355(b)(2) or (j) [21 U.S.C. § 355, regulating NDA and ANDA submissions] or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application." 21 U.S.C. § 355-1(f)(8).

52. Reckitt knew that if it did not sabotage the FDA-required process, the required joint REMS would quickly be completed, and the FDA would likely approve the generic Suboxone tablets for sale no later than May 2012. Reckitt's problem was that, by May 2012, it would have successfully converted only about 50% of its Suboxone unit sales from the tablet to the film. This would have left more than \$500 million of Reckitt's annual Suboxone tablet sales vulnerable to immediate loss to generic competition. Reckitt therefore decided to sabotage the REMS process and thereby delay FDA approval of the generics and get more time to switch additional prescriptions from the tablets to the film.

53. To illustrate, on January 6, 2012, FDA sent all Suboxone generic ANDA filers a REMS Notification Letter explaining that these drug products would be subject to a Single Shared REMS (SSRS) program. The Notification Letter advised all ANDA filers to contact Reckitt to collaborate on the creation and implementation of an SSRS program. The Notification

Letter also stated that the REMS should address pediatric exposures. FDA mandated a compliance date of May 6, 2012, for approved products, by which time it expected that the SSRS with Reckitt would be accomplished. The deadline set by the FDA demonstrated the agency's expectation that Reckitt's own previously-approved Suboxone REMS could be amended to add generic manufacturers in a relatively short time. Instead of coordinating its efforts and resources with ANDA applicants, however, Reckitt unilaterally retained the services of the Researched Abuse, Diversion and Addiction-Related Surveillance System and Venebio Group, LLC and Venebio Group to prepare a study on the risk of pediatric exposure to Suboxone tablets, not Suboxone films. Reckitt's goal in retaining these firms to conduct a study regarding only Suboxone tablets is obvious. Reckitt was mobilizing its resources to ensure blocking, or at least delaying, ANDA applications.

54. Furthermore, Reckitt, knowing that a joint submission to the FDA was the final prerequisite to FDA approval of the pending Suboxone tablet ANDAs, and realizing that it was a required participant, sabotaged the joint process through unjustifiable and baseless delay tactics, flat refusals to participate, and pretextual conditions on participation—all nothing more than thin excuses intended to disguise its transparently anticompetitive intentions, in violation of 21 U.S.C. § 355-1(f)(8).

55. Reckitt's sabotage of the joint process was documented in writing by the various generic manufacturers holding Suboxone tablet ANDAs. Those manufacturers were Actavis, Inc., Amneal Pharmaceuticals LLC, Ethypharm USA Corp., Mylan Inc., Roxane Laboratories Inc., Sandoz Inc., Sun Pharmaceuticals Industries, Ltd., and Teva Pharmaceuticals USA, Inc. One or more of those manufacturers have reported to the FDA that Reckitt:

- a. merely feigned cooperation with the shared REMS development process;



- b. refused to participate in meetings with the generic ANDA filers;
- c. refused to discuss any substantive issues with the generic ANDA filers pertaining to the shared REMS when it did attend meetings;
- d. placed unreasonable conditions on its cooperation with the shared REMS development process that it knew the ANDA filers could not agree to (such as to assume Reckitt's tort liability by contract, which had nothing to do with the development of a joint REMS and would have caused the ANDA filers' liability insurers to disclaim coverage);
- e. refused to sign the governing memorandum of understanding for the ANDA filers unless Reckitt was given *veto* authority or *super-majority* vote for all issues relating to SSRS;
- f. insisted that ANDA filers agree to pre-specified percentage of product liability claims regardless of fault;
- g. refused to share information with the generic ANDA filers about the existing REMS program that was essential to the shared REMS development process—despite having entered into confidentiality agreements with ANDA filers;
- h. raised a last-minute issue merely to cause still further delay just before a shared REMS was to be submitted to FDA in August 2012; and
- i. stopped participating altogether in September 2012.

56. Reckitt's sabotage of the shared REMS development process was intended to, and did, delay FDA's approval of one or more Suboxone tablet ANDAs.

57. On May 6, 2012, and as a result of Reckitt's actions, ANDA filers jointly requested a meeting with the FDA to discuss the delays created by Reckitt. The FDA scheduled a meeting on June 18, 2012 and invited all ANDA filers and Reckitt. During the meeting, and after reviewing all written material and communications, and after hearing each party's oral presentation, the FDA agreed with ANDA filers that Reckitt was creating and causing delays to ANDA applications. To mitigate the conflict, the FDA asked ANDA filers and Reckitt to develop a new SSRS based upon the requirements set forth in the REMS Notification Letter, without using any of Reckitt's existing information.

58. Reckitt advised the FDA at the meeting that it would cooperate with the ANDA filers to develop this new SSRS, which Reckitt knew was necessary for generic manufacturers to obtain approval of their respective ANDAs. But Reckitt's participation in the new SSRS process was for different reasons. Despite its commitment to cooperate, Reckitt's goal was solely to maintain its access to proprietary information regarding ANDA applicants' filing status, timing, and content of the proposed new SSRS. This is evident by Reckitt's continued intransigence and delay tactics.

59. For example, in mid-August 2012, ANDA filers filed the SSRS with the FDA as part of their respective applications. Reckitt refused to submit the new SSRS with its own New Drug Application ("NDA"). Instead, Reckitt suddenly, and only two days before the scheduled submission of the REMS documents to the FDA, raised an issue regarding a prescriber outreach component of the SSRS involving the use of a field force, arguing that the generic manufacturers had omitted an important element of the REMS. This was yet another element in Reckitt's overall campaign to delay FDA approval of generic Suboxone tablets.

#### **F. Step Four: Reckitt Files a Sham Citizen Petition**

60. Persons can submit a Citizen Petition to the FDA at any time in order to express genuine concerns about safety, scientific, or legal issues regarding a product. Under these regulations, any person or entity, including a pharmaceutical manufacturer, may file a Citizen Petition with the FDA requesting that the FDA take, or refrain from taking, any administrative action. The person or entity submitting such a petition is required, under FDA regulations, to include all information and views on which the petitioner relies, as well as all information and data known to the petitioner which is unfavorable to the petition.

61. Federal regulations provide a 180-day period for the FDA to respond to each Citizen Petition. 21 C.F.R. § 10.30. The FDA usually takes much more than 180 days, however, because reviewing and responding to these petitions is often a resource-intensive and time-consuming task requiring the FDA, in addition to its already-existing workload, to (a) research the relevant subject matter, (b) examine scientific, medical, legal, public health, and safety concerns, and occasionally economic issues, (c) consider public responses, and (d) coordinate internal agency review and clearance of the petition response.

62. These activities strain the FDA's resources. It was the well-known practice of the FDA during the Class Period to consider and respond to a Citizen Petition before approving an ANDA product that is the subject of the petition and to delay approval of the ANDA pending response to the petition, particularly when it had been filed by a brand manufacturer asserting (whether correctly or not) a public health or safety concern.

63. Brand drug manufacturers commonly use the filing of Citizen Petitions as a tactic to extend their monopolies. Taking advantage of FDA's practice of delaying ANDA approvals while it evaluates petitions, brand manufacturers have routinely submitted petitions to the FDA that do not raise legitimate concerns about the safety or effectiveness of generic products. This tactic delays final ANDA approval, sometimes for substantial periods, while the FDA evaluates the petition.

64. The brand manufacturer's cost of filing sham Citizen Petitions is trivial compared to the value to the manufacturer of securing an additional period of monopoly profits.

65. All of this is common knowledge in the pharmaceutical industry.

66. FDA officials have acknowledged ongoing abuses of the petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency, he had "seen several

examples of Citizen Petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before.”

67. In July 2006, Gary Buehler, Director of the FDA’s Office of Generic Drugs, Center for Drug Evaluation and Research, testifying before Congress regarding brand manufacturers’ abuses of the Citizen Petition process, stated that of forty-two Citizen Petitions raising issues about the approvability of generic products, “very few . . . have presented data or analysis that significantly altered FDA’s policies.” Of these forty-two petitions, only three led to a change in the FDA’s policy on the basis of data or information submitted in the Citizen Petition.

68. Other federal agencies have also recognized brand manufacturers’ abuse of the petition process. The Federal Trade Commission’s then-Chairman, Jon Leibowitz, stated that the petition process is “susceptible to systematic abuse,” and that “[i]t is no coincidence that brand companies often file these petitions at the eleventh hour before generic entry and that the vast majority of citizen petitions are denied.”

69. After generic Suboxone tablet ANDA filers submitted a shared REMS program of their own to the FDA in August 2012, Reckitt knew that the FDA would likely accept the generics-only shared REMS, as submitted or with modification, and then quickly approve one or more generic Suboxone tablet ANDAs. But Reckitt needed still more time to finalize its anticompetitive product hop. By September 2012, Reckitt still had converted only about 70% of

the Suboxone unit sales from tablets to the film. This left a still-hefty \$300 million of Reckitt's annual Suboxone revenue vulnerable to imminent loss to generic competition.

70. Reckitt therefore implemented yet another anticompetitive delaying tactic. On September 25, 2012—when Reckitt knew that FDA approval of generic Suboxone tablets was imminent—Reckitt announced its intent to permanently withdraw Suboxone tablets from the market for purported public safety reasons, and also filed an objectively baseless Citizen Petition with the FDA. Reckitt failed to disclose any of these alleged safety issues to the generic manufacturers during the REMS negotiations. After ten years on the market, and just as the FDA was ready to finally approve generic Suboxone tablets, Reckitt suddenly discovered a safety issue so severe that it purportedly required the removal of Suboxone tablets from the market within the next six months.

71. While Reckitt's positions set forth in the petition were wholly devoid of merit, the FDA could not approve the pending generic Suboxone tablet ANDAs without assuring itself that Reckitt's petition was baseless, which the FDA did on February 22, 2013. In the meantime, however, Reckitt made over another \$400 million in Suboxone sales during that five-month delay.

72. Reckitt's petition asked the FDA to withhold approval of generic Suboxone tablet ANDAs unless: (1) the ANDA contains a targeted pediatric exposure education program; and (2) the ANDA product has child-resistant unit-dose packaging. Reckitt's petition also asked that the FDA refrain from approving any generic Suboxone tablet ANDA until it determined whether Reckitt discontinued the Suboxone brand tablet for safety reasons. Reckitt claimed it would cease distribution of Suboxone tablets on March 18, 2013.

73. Reckitt filed the petition for the sole purpose of delaying generic competition. Reckitt's prior tactic of sabotaging the shared REMS process had run its course. At no time during that process did Reckitt share with the generic ANDA filers any of the information contained in Reckitt's Citizen Petition. Instead, Reckitt kept its petition and its contents a tactical surprise. Given the purported safety-related bases of Reckitt's petition, Reckitt's secrecy—as well as its failure to take the very actions to protect patients that it sought to require of the generic tablet sellers—exposes the tactical, anticompetitive nature of the petition. Manufacturers with genuine safety concerns do not keep them a secret. Manufacturers with genuine safety concerns seek to adjust their own existing products, not just the products of competitors.

74. Reckitt's petition was also objectively baseless. No reasonable petitioner could realistically expect to succeed on the merits of the petition Reckitt filed. Reckitt's petition lacked any reasonable regulatory, scientific, medical, or other basis. The FDA lacked the statutory authority to withhold approval of generic Suboxone tablet ANDAs on the bases cited by Reckitt, or to require the actions Reckitt sought to impose on the ANDA filers. Reckitt's petition lacked clinically meaningful evidence that supported its assertions or that bore on the approvability of generic Suboxone ANDAs. Reckitt's petition stood no chance of affecting the FDA policy or procedure. In short, it was a sham.

75. Evidence demonstrating the absence of a reasonable basis for Reckitt's petition abounds. Regarding Reckitt's pediatric exposure education program, there existed no statutory or regulatory basis for requiring its inclusion in any Suboxone ANDA. Reckitt had not included such an education program in its own NDA or any supplement to its NDA, nor is there any statutory or regulatory authority for the FDA to require an ANDA filer, as a condition of

approval, to create labeling or REMS materials that are different from those approved for the reference drug.

76. Not only was Reckitt's petition objectively baseless, but Reckitt did not even believe its own words. On August 30, 2012—just over three weeks before Reckitt submitted its Citizen Petition on September 25, 2012—Reckitt represented to the FDA in a combined REMS assessment that the tablet REMS was successful and needed no further changes. Reckitt's statements to the contrary in its Citizen Petition were not only false, but Reckitt knew them to be false when it made them.

77. Regarding unit-dose packaging, Reckitt's petition did not acknowledge the FDA's previously stated positions, but instead flatly ignored them. Reckitt knew from a letter the FDA wrote to it in March 2010 that the FDA had long since concluded that, because of the high percentage of patients who took Suboxone in divided daily doses, unit-dose packaging did not ameliorate, and might even exacerbate, the known incidence of accidental pediatric buprenorphine exposure. "Because patients are known to divide tablets, it may be expected that patients will remove films from the package and have partial doses that are neither in the child-resistant pouch nor in a child-resistant medication bottle," the FDA said.

78. The FDA's denial of Reckitt's Citizen Petition underscores that no reasonable petitioner could have expected to succeed on the merits. The FDA found or noted each of the following facts: (a) the petition was not supported by any evidence that the educational programs or unit-dose packaging Reckitt sought to require of ANDA-filers caused a decline in accidental pediatric exposures; (b) as Reckitt admitted, the study upon which it relied did not even evaluate the impact of educational programs or packaging on pediatric exposure, and thus there was insufficient information to reach conclusions about those measures; (c) the Food Drug &

Cosmetic Act does not require that ANDA holders implement activities and/or distribute materials that the FDA has concluded are not required for the safe and effective use of the reference listed product; (d) in addition to providing no evidence that unit-dose packaging caused a decline in accidental pediatric exposure, the petition was premised on unsupported assumptions that unit-dose packaging of Suboxone is safer, when the available data actually shows the opposite; and (e) Reckitt's own conduct was contrary to arguments made in its petition.

79. Regarding the issue of whether Reckitt's planned removal of Suboxone tablets from the market was for reasons of safety, there exist no statutory or regulatory grounds for the FDA to rule on the basis for a manufacturer's withdrawal of a product from the market before that withdrawal occurs. Similarly, there exist no statutory or regulatory grounds for the FDA to rule that the container closure system employed to package a drug—the sole basis upon which Reckitt premised its request—required withdrawal of a product. And as Reckitt well knew, and as alleged in detail above, Reckitt planned to remove Suboxone tablets from the market not to protect children, but to protect its revenues from generic competition. Reckitt simply lied to the FDA.

80. On February 22, 2013, the FDA denied Reckitt's petition in its entirety. In rejecting Reckitt's requests that ANDA filers be required to establish additional "education initiatives" (which were not a part of its own approved REMS) and market generic Suboxone products in unit-dose packaging, the FDA explained that: (1) the data did not support Reckitt's conclusion that its optional "educational interventions" were the cause of decreased pediatric exposures; and (2) the data did not support Reckitt's purported concerns regarding "unit-dose packaging" because, among other things, the vast majority of pediatric exposure incidents came



from *single or partial* doses of Suboxone—exposures that would not be affected or deterred at all by a unit-dose packaging requirement.

81. Even the FDA recognized and exposed the pretextual nature of Reckitt's petition.

The FDA observed:

Since approval of the SUBOXONE film REMS in 2010 (and subsequent approval of the same REMS for SUBOXONE and SUBUTEX tablets in 2011), Reckitt has not proposed any revisions to the REMS for these products to further address the risk of accidental pediatric exposure. In its August 30, 2012, combined REMS assessment for these products, which contained poison control center data and information gathered from surveys of patients and prescribers through that time, Reckitt stated that the REMS for SUBOXONE had been successfully implemented and that it was not proposing any changes.

The FDA further added, “[t]he timing of Reckitt’s September 2012 announcement that it would discontinue marketing of the tablet product because of pediatric exposure issues, given its close alignment with the period in which generic competition for this product was expected to begin, cannot be ignored.”

82. As to Reckitt’s final argument that federal regulations prohibited the FDA from approving generic Suboxone tablets without first determining whether Reckitt had withdrawn Suboxone from the market for safety or efficacy reasons, the FDA had a simple answer: *Reckitt had not withdrawn the tablets from the market.* The FDA noted that Reckitt declared its *intention* to withdraw from the market, but its products were still being shipped and sold, therefore the FDA was not obligated to make “[a] determination whether a listed drug that has been voluntarily withdrawn from sale was withdrawn for safety or effectiveness reasons may be made by the agency at any time after the drug has been voluntarily withdrawn from sale, but must be made: Prior to approving an abbreviated new drug application that refers to the listed

drug.” 21 C.F.R. 314.161(a)(1). The FDA then affirmatively stated that withdrawal of the Suboxone tablets was not necessary for reasons of safety.

**G. The Same Reckitt Decisionmakers Approved Other Anticompetitive Product Hops at the Same Time.**

83. Upon information and belief, the Board of Directors of Defendant Reckitt Benckiser Group plc (“Board of Directors”) were advised of the generic-impairing purpose of the product hop from Suboxone tablets to film, and of the related anticompetitive tactics, and specifically approved the scheme and its purpose. The Board of Directors approved and directed this anticompetitive scheme over the course of many years, including the period encompassing the mid-2000s.

84. During this same time period, the Board of Directors also approved and directed at least one other anticompetitive product hop. On April 12, 2011, the United Kingdom’s Office of Fair Trading (“OFT”) issued a decision finding Reckitt Benckiser Group plc (“RBG”) liable for abuse of its dominant position in the relevant market in the UK. *Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc*, Decision No. CA98/02/2011; Case CE/8931/08 (OFT April 12, 2011) (“Decision”). The competition agency found that the Board of Directors had specifically approved an anticompetitive scheme whereby RBG, among other things, withdrew one formulation of its Gaviscon product from the market as part of a product hop to a follow-on, patent-protected version of the product.

85. The anticompetitive scheme that the Board of Directors approved and directed with respect to the Gaviscon product hop is strikingly similar to the scheme that it approved and directed with respect to Suboxone in or around the same time. The OFT found for example:

- The evidence “demonstrates the involvement of senior management including members of the Board and/or Executive Committee of Reckitt Benckiser Group plc (and its predecessor, Reckitt Benckiser plc) in the decision making process relevant to the [actionable] conduct....” Decision, at 3.21.
- Reckitt “concluded that attempting to justify the timing of the Withdrawal on the basis of a business rationale alone would be risky. With the assistance of [Reckitt’s] PR agency, a series of communications plans were devised, in which various explanations for the Withdrawal were prepared and tailored in respect of the different sets of stakeholders.” Decision, at 2.198.
- Among the “various explanations” that Reckitt cooked up for the anticompetitive scheme was a purported safety concern. Reckitt asserted that the reformulated product “was lower in sodium than [the original product], and therefore had safety advantages in relation to, for example, patients with dyspepsia or hypertension.” Decision, at 2.200.
- The OFT concluded that Reckitt’s “safety” rationale was pretextual because, among other reasons, Reckitt did not withdraw the higher-sodium product from the over-the-counter market where Reckitt had no ability to thwart generic competition. Decision, at 2.214.

86. The OFT considered the totality of the evidence in reaching the conclusion that Reckitt had withdrawn the original product in order to impair generic competition. Decision, at 6.29. The Reckitt internal documents quoted in the decision make Reckitt’s purpose unmistakably clear, and show its alleged safety concern to be a farce. For example:

- A March 2004 memorandum left no doubt as to Reckitt’s sole purpose: “The objective of the [New Product Development] is to replace/cannibalise all current 500ml Gaviscon Liquid sales ... in the NHS [National Health Service] with the new patent protected variant. [Reckitt] will drive this cannabilitation through the withdrawal of the current Gaviscon Liquid SKUs from sale in parallel to the launch of the new SKUs. ... [O]ur ultimate objective is to force cannabilitation of our exposed NHS business into a protected variant more efficiently than has been achieved since the launch of Gaviscon Advance.” Decision, at 2.164. “Cannibalise” is the industry term for urging doctors to switch prescriptions and prescribing habits from the original brand product to the reformulated product.
- A January 2000 email had emphasized the need for delaying tactics while Reckitt “cannibalized” the sales of the original product: “We should remind ourselves what our objective is here ... to delay for as long as possible, the introduction of [generic competition for] Gaviscon while we cannibalise our NHS franchise with Gaviscon Advance.” Decision, at 2.136.

- An April 2003 email made unmistakably clear the pretextual nature of Reckitt's alleged safety concern: "If we were to change the formulation of our current Gaviscon liquid ... with the rationale that we were doing so for health and safety reasons ... we could withdraw Gaviscon liquid from sale within the NHS and replace it with the new formulation." Decision, at 2.142.
- A March 2005 presentation to the Board of Directors specifically referred to the scheme as the best way to protect Gaviscon from full generic competition: "Full agreement that we must implement [the scheme] in 2005 before a generic name is granted. ... Business will continue to place max focus on strategies to delay generic name in the interim...." Decision, at 2.194.

87. In October 2010, Reckitt admitted violating UK competition laws by abusing its dominant position through the Gaviscon scheme. Reckitt also agreed to pay a substantial penalty. Reckitt clearly followed the Gaviscon template in forming and implementing the similarly anticompetitive Suboxone scheme.

#### **H. Reckitt's Scheme Was Intended To, And Did, Harm Competition**

88. As intended, Reckitt's scheme, as a whole and in its individual parts, blocked and delayed generic Suboxone competition by excluding would-be generic competitors from the most efficient means of distributing their products.

89. Reckitt's exclusionary motive is illustrated by its willingness to sacrifice short-term profits as part of its product hop strategy. Reckitt's decisions to incur the extra costs (and suffer the revenue losses) associated with the change in Suboxone's dosage form from tablets to film and the discontinuation of Suboxone tablets were economically rational only because those changes had the exclusionary effect of suppressing generic competition. But for the impact on generic competition, Reckitt would not have invested the resources necessary to develop Suboxone film and destroy the prescription base for Suboxone tablets, because it would have been economically irrational to do so.

90. Reckitt's unjustifiable delay and refusal to cooperate with the generic ANDA filers in the joint REMS process mandated by the FDA, in violation of 21 U.S.C. § 355-1(f)(8), directly prevented the generic ANDA filers from obtaining the FDA approval. But for Reckitt's unlawful conduct, the FDA would have approved one or more generic Suboxone tablets no later than May 2012.

91. Reckitt's baseless, sham Citizen Petition further delayed FDA approval of generic Suboxone tablets. But for Reckitt's sham filing, the FDA would have approved one or more generic Suboxone tablets no later than September 2012.

92. To the extent it is even permitted to do so, Reckitt cannot justify its scheme by pointing to any offsetting consumer benefit. The enormous cost savings offered by generic drugs (and, correspondingly, the anticompetitive harm caused by suppressing generic competition to Suboxone) outweigh any cognizable, nonpretextual procompetitive justifications Reckitt could possibly offer.

93. Any justifications Reckitt could offer for its scheme are, in fact, pretexts. And, whatever justifications Reckitt may offer, Reckitt did not need to engage in the conduct challenged in this lawsuit to achieve them.

94. If Reckitt were simply interested in introducing a new Suboxone film product to compete on the merits with Suboxone tablets, it could have done so without taking the additional, affirmative steps described herein to: (a) delay the market entry of less-expensive generic versions of Suboxone tablets; (b) interfere with the normal competition that routinely occurs between branded products and their generic counterparts as contemplated by the Hatch-Waxman Act; and (c) destroy the prescription base for Suboxone tablets.

95. If Reckitt were simply and solely interested in modifying the container closure system for Suboxone in the United States to contain a unit-dose packaging feature, it could have done so, as it has done in several other countries since 2005, without reformulating Suboxone's dosage form into a film and thereby destroying the automatic substitutability of Suboxone tablets.

96. As a result of its illegal scheme, Reckitt: (1) illegally maintained and extended its monopoly in the market for Co-Formulated Buprenorphine/Naloxone; (2) fixed, raised, maintained, and/or stabilized the price of Co-Formulated Buprenorphine/Naloxone at supra-competitive levels; and (3) overcharged Plaintiffs and other end-payors of Suboxone by hundreds of millions of dollars by depriving them of the benefits of competition from cheaper generic versions of Suboxone.

97. Reckitt maintained its monopoly power, as alleged more fully below, through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a superior product, business acumen or historic accident. Neither Reckitt's scheme as a whole, nor any of its constituent parts, constituted competition on the merits.

98. As alleged in more detail below, Reckitt violated the state statutes and common law enumerated below through its overarching scheme to improperly maintain and extend its monopoly power by foreclosing or delaying competition from lower-priced generic versions of Suboxone.

### **III. JURISDICTION AND VENUE**

99. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000 and at least one member of the putative class is a citizen of a state different from that of Reckitt.

100. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy the Defendants' violations of Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. The Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367.

101. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §1391(b) and (c), because Defendants transact business within this district, and/or have an agent and/or can be found in this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

#### **IV. THE PARTIES**

102. Plaintiff A.F. of L. – A.G.C. Building Trades Welfare Plan (the “A.F.L. Plan”) maintains its principal place of business in Mobile, Alabama. Plaintiff has purchased and/or provided reimbursement for some or all of the purchase price for Suboxone, other than for re-sale, in Alabama, California, Florida, Iowa, Mississippi, and Nevada, at supra-competitive prices during the Class Period and has thereby been injured. Plaintiff purchased generic Suboxone, other than for re-sale, once it became available.

103. Plaintiff I.B.E.W. 292 Health Care Plan maintains its principal place of business in Minneapolis, Minnesota. Plaintiff has purchased and/or provided reimbursement for some or all of the purchase price for Suboxone, other than for re-sale, in Minnesota at supra-competitive prices during the Class Period and has thereby been injured. Plaintiff purchased generic Suboxone, other than for re-sale, once it became available.

104. Plaintiff Meridian Health Plan of Michigan, Inc. maintains its principal place of business in Detroit, Michigan. Plaintiff has purchased and/or provided reimbursement for some

or all of the purchase price for Suboxone, other than for re-sale, in Michigan at supra-competitive prices during the Class Period and has thereby been injured. Plaintiff purchased generic Suboxone, other than for re-sale, once it became available.

105. Plaintiff Michigan Regional Council of Carpenters Employee Benefits Fund maintains its principal place of business in Troy, Michigan. Plaintiff has purchased and/or provided reimbursement for some or all of the purchase price for Suboxone, other than for re-sale, in Michigan, Kentucky, and Ohio, at supra-competitive prices during the Class Period and has thereby been injured. Plaintiff purchased generic Suboxone, other than for re-sale, once it became available.

106. Plaintiff New York Hotel Trades Council & Hotel Assoc. of New York City, Inc. Health Benefits Fund (“NYHTC”) maintains its principal place of business in New York. Plaintiff has purchased and/or provided reimbursement for some or all of the purchase price for Suboxone, other than for re-sale, in New York at supra-competitive prices during the Class Period and has thereby been injured. Plaintiff purchased generic Suboxone, other than for re-sale, once it became available.

107. Plaintiff Painters District Council No. 30 Health and Welfare Fund (“Painters Fund”) maintains its principal place of business in Aurora, Illinois. Plaintiff has purchased and/or provided reimbursement for some or all of the purchase price for Suboxone, other than for re-sale, in Alaska, Illinois, Michigan, Missouri, Ohio, and Wisconsin at supra-competitive prices during the Class Period and has thereby been injured. Plaintiff purchased generic Suboxone, other than for re-sale, once it became available.

108. Plaintiff Teamsters Health Services and Insurance Plan Local 404 maintains its principal place of business in Springfield, Massachusetts. Plaintiff has purchased and/or provided



reimbursement for some or all of the purchase price for Suboxone, other than for re-sale, in Massachusetts and New Jersey at supra-competitive prices during the Class Period and has thereby been injured. Plaintiff purchased generic Suboxone, other than for re-sale, once it became available.

109. Plaintiff Construction & General Laborers' Local 190 Welfare Fund maintains its principal place of business in Glenmont, New York. Plaintiff has purchased and/or provided reimbursement for some or all of the purchase price for Suboxone, other than for re-sale, in New York at supra-competitive prices during the Class Period and has thereby been injured. Plaintiff purchase generic Suboxone, other than for re-sale, once it became available.

110. Plaintiff United Food and Commercial Workers Health and Welfare Fund of Northeastern Pennsylvania maintains its principal place of business in Plymouth Meeting, Pennsylvania. Plaintiff has purchased and/or provided reimbursement for some or all of the purchase price for Suboxone, other than for re-sale, in Pennsylvania at supra-competitive prices during the Class Period and has thereby been injured. Plaintiff purchased generic Suboxone, other than for re-sale, once it became available.

111. Defendant Reckitt Benckiser Inc. is a Delaware corporation with its principal place of business located at Morris Corporate Center IV, 399 Interpace Parkway, Parsippany, New Jersey 07054. This defendant manufactures and markets numerous consumer products, including pharmaceutical drugs subject to FDA approval, and was responsible for the conduct alleged herein.

112. Defendant Reckitt Benckiser LLC is a Delaware limited liability company with its principal place of business located at Morris Corporate Center IV, 399 Interpace Parkway, Parsippany, New Jersey 07054. This defendant manufactures and markets numerous consumer

products, including pharmaceutical drugs subject to FDA approval, and was responsible for the conduct alleged herein.

113. Defendant Reckitt Benckiser Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located at The Fairfax Building, 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235. This defendant manufactures and markets numerous consumer products, including pharmaceutical drugs subject to FDA approval, and was responsible for the conduct alleged herein.

114. Defendant Reckitt Benckiser Healthcare (UK) Ltd. is a British corporation incorporated under the laws of England and Wales, with its registered office located at Dansom Lan, Hull, North Humberside HU8 7DS. This defendant manufactures and markets numerous consumer products, including pharmaceutical drugs subject to FDA approval, and was responsible for the conduct alleged herein.

115. Defendant Reckitt Benckiser Group plc is a British corporation incorporated under the laws of England and Wales, with its registered office located at Turner House, 103-105 Bath Road, Slough, Berkshire, SL1 3UH, England. This defendant manufactures and markets numerous consumer products, including pharmaceutical drugs subject to FDA approval, and was responsible for the conduct alleged herein.

116. All of Reckitt's actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by Reckitt's various officers, agents, employees, or other representatives while actively engaged in the management of Reckitt's affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Reckitt.

## **V. CLASS ACTION ALLEGATIONS**

117. Plaintiffs brings this action on their own behalves and, under Rules 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, as representatives of a Class defined as follows:

All persons or entities who purchased and/or paid for some or all of the purchase price for Co-Formulated Buprenorphine/Naloxone in any form, in the United States and its territories for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period December 22, 2011 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class").

118. The following persons or entities are excluded from the proposed Class:

- a. Reckitt and their officers, directors, management, employees, subsidiaries, or affiliates;
- b. All governmental entities, except for governmental funded employee benefit plans;
- c. All persons or entities who purchased Co-Formulated Buprenorphine/Naloxone for purposes of resale or directly from Defendants or their affiliates;
- d. Fully insured health plans (i.e., Plans that purchased insurance from another third party payor covering 100% of the Plan's reimbursement obligations to its members);
- e. Any "flat co-pay" consumers whose purchases of Suboxone were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price;
- f. Any "brand loyalist" consumers or third-party payors who did not purchase any AB-rated generic Suboxone equivalent after such generics became available; and
- g. The judges in this case and any members of their immediate families.

119. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

120. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct by Reckitt, *i.e.*, they paid artificially inflated prices for Co-Formulated Buprenorphine/Naloxone products and were deprived of the benefits of competition from less-expensive generic versions of Suboxone tablets as a result of Reckitt's wrongful conduct.

121. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

122. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

123. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Reckitt has acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Reckitt's wrongful conduct.

124. Questions of law and fact common to the Class include:

- a. whether Reckitt unlawfully maintained monopoly power through all or part of its overarching scheme;
- b. whether Reckitt's anticompetitive scheme suppressed generic competition to Suboxone;
- c. whether Reckitt's introduction of Suboxone film and destruction of the prescription base for Suboxone tablets was predatory and anticompetitive;
- d. whether Reckitt's sabotage of the development process for a shared REMS was anticompetitive;
- e. whether a reasonable petitioner would have expected the arguments made in Reckitt's Citizen Petition to succeed;
- f. whether Reckitt submitted the Citizen Petition for the purpose of interfering with competition;

- g. as to those parts of Reckitt's challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Reckitt's challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the market(s) in which Suboxone is sold;
- h. whether direct proof of Reckitt's monopoly power is available, and if available, whether it is sufficient to prove Reckitt's monopoly power without the need to also define a relevant market;
- i. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
- j. whether Reckitt's scheme, in whole or in part, has substantially affected interstate commerce;
- k. whether Reckitt's scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiffs and the members of the Class in the nature of overcharges; and
- l. the quantum of overcharges paid by the Class in the aggregate.

125. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

126. With their conduct alleged herein, the Defendants have acted or refused to act on grounds that apply generally to the Class, so that final injunctive relief (or corresponding declaratory relief) is appropriate respecting the Class as a whole.

127. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

## **VI. OTHER FACTUAL ALLEGATIONS**

### **A. Characteristics of the Pharmaceutical Marketplace**

128. The marketplace for the sale of prescription pharmaceutical products in the United States contains a significant feature that can be exploited by manufacturers in order to extend a monopoly in the sale of a particular pharmaceutical composition. In most industries, the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the person's choice of products and, consequently, manufacturers have a strong incentive to lower the price of their products in order to maintain profitability.

129. The pharmaceutical marketplace, by contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Co-Formulated Buprenorphine/Naloxone, to patients without a prescription written by the patient's physician. The prohibition on dispensing certain products without a prescription introduces a "disconnect" in the pharmaceutical marketplace between the payment obligation and the product selection. The patient (and in many cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's physician chooses which product the patient will buy.

130. Many pharmaceutical manufacturers, including Reckitt, exploit this feature of the pharmaceutical marketplace. The so-called "brand manufacturers" (*i.e.*, the manufacturers of branded, as opposed to generic, pharmaceuticals) employ large forces of sales representatives, known as "detailers," who visit physicians' offices in an effort to persuade physicians to prescribe the manufacturer's products. Importantly, these detailers do not advise the physicians of the cost of the branded products. Studies show that physicians typically are not aware of the

relative costs of branded pharmaceutical products and that, even when physicians are aware of the relative cost, they are insensitive to price differences, because they do not pay for the products themselves. The result is a marketplace in which price often plays a comparatively unimportant role in product selection.

131. In situations in which two manufacturers each sell a drug that serves a similar medical function and each manufacturer uses a significant detailer force, those products are often sold at very similar, high prices, thus eliminating any consumer benefit from that “competition.” This is in stark contrast to the situation in which the competing seller of an AB-rated, bioequivalent drug is a generic manufacturer without a detailer force. In that case, the generic price is significantly lower than the brand price, and consumers benefit as Congress intended by the Hatch-Waxman Act, discussed below.

132. When the relative importance of the price between two branded pharmaceuticals, or pharmaceuticals that otherwise are not AB-rated to one another, is low, the price elasticity of demand—the extent to which sales go down when price goes up—is by definition also low, which in turn gives brand manufacturers the ability to raise or maintain price substantially above competitive levels without losing so many sales that the price increase becomes unprofitable. The ability to raise price above competitive levels without losing so many sales as to make the price increase unprofitable, is referred to by economists and antitrust courts as market power or monopoly power. Thus, the net result of the pharmaceutical industry features and marketing practices described above often is to allow brand manufacturers to gain and maintain monopoly power.

133. Congress sought to ameliorate the “disconnect,” and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by authorizing the manufacture and

sale of generic pharmaceuticals under the Hatch-Waxman Act, discussed below. When a pharmacist receives a prescription for a branded pharmaceutical product, and an AB-rated generic version of that product is available, state laws permit (or in some cases require) the pharmacist to dispense the generic product in lieu of the branded product. In this way, the importance of price is reintroduced to the product selection decision at the pharmacy counter, and the pharmaceutical marketplace “disconnect” is ameliorated. When an AB-rated generic product is introduced and is not prevented from competing unfettered, branded pharmaceutical manufacturers are no longer able to exploit these unique features of the pharmaceutical marketplace, their monopoly power dissipates, and some of the normal competitive pressures are restored.

134. If Reckitt’s unlawful conduct had not delayed generic manufacturers from successfully entering the market with generic versions of Suboxone tablets, end-payors like Plaintiffs and members of the Class would have saved hundreds of millions of dollars in purchases of Co-Formulated Buprenorphine/Naloxone. Reckitt’s anticompetitive scheme purposely impaired and delayed generic competition to Suboxone.

**B. The Regulatory Structure Pursuant to Which Generic Substitutes for Brand-Name Drugs Are Approved**

135. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301-392 (“FDCA”), manufacturers who create a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing an NDA. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.



136. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (“Hatch-Waxman”).

137. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain the FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an ANDA.

138. The ANDA relies on the scientific findings of safety and effectiveness included by the brand-name drug manufacturer in the original NDA.

139. In order to be substitutable for a branded product at the pharmacy counter, and approvable by the FDA as AB-rated to a particular branded product, a generic product must be, among other things, “pharmaceutically equivalent” (same dosage form and strength) and “bioequivalent” (exhibiting the same drug absorption characteristics) as the branded product.

**C. Generic Versions of Brand-Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand-Name Versions**

140. Typically, generic versions of brand-name drugs are priced significantly below the brand-name versions. Because of the price differentials, and other institutional features of the pharmaceutical industry, generic versions are liberally and substantially substituted for their brand-name counterparts. In particular, generic drugs that are pharmaceutically equivalent and bioequivalent (together, “therapeutically equivalent”) to their brand name counterparts are given an “AB” rating by the FDA. Pharmacists substitute an AB-rated generic product for the corresponding brand-name product unless the doctor has indicated that the prescription for the brand-name product must be dispensed as written. As more generic manufacturers enter the

market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics accelerates.

141. Reckitt was well aware of this impending loss of Suboxone sales volume. As reflected in Reckitt's 2008 Annual Report, Reckitt knew that Suboxone tablets would lose 80% or more of their sales to less-expensive generic equivalents within the first year of competition, and that it stood to lose hundreds of millions of dollars after generic Suboxone tablets entered the market.

142. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of a drug at substantially lower prices; and/or (b) purchase the brand-name drug at a reduced price. Until a generic manufacturer enters the market, however, there is no bioequivalent generic drug to compete with the brand-name drug, and therefore the brand-name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales. Consequently, brand-name drug manufacturers have a strong incentive to use various tactics, including those alleged above, to delay the introduction of generic competition into the market.

#### **D. Effects on Competition and Damages to Plaintiff and the Class**

143. Reckitt's overarching anticompetitive scheme impaired and delayed the sale of generic Suboxone tablets in the United States, and unlawfully enabled Reckitt to sell Suboxone at artificially inflated prices. But for Reckitt's illegal conduct, generic competitors would have been able to compete, unimpeded, with generic versions of Suboxone tablets.

144. If manufacturers of generic Suboxone tablets had been able to enter the marketplace and effectively compete with Reckitt earlier or without Reckitt's having switched

the market to Suboxone film, as set forth above, Plaintiffs and other members of the Class would have: (1) substituted lower-priced generic Suboxone tablets for the higher-priced brand-name Suboxone tablets for some or all of their Co-Formulated Buprenorphine/Naloxone requirements; (2) paid a lower price for their generic Co-Formulated Buprenorphine/Naloxone products, sooner; and/or (3) paid lower prices for some or all of their remaining branded Suboxone purchases.

145. Reckitt's scheme, however, has impaired and delayed the FDA approval of the generic products, and deprived the manufacturers of generic Suboxone tablets of the cost-efficient means of distribution, thus artificially limiting the pool of potential generic tablet prescriptions to a small fraction of the total Co-Formulated Buprenorphine/Naloxone prescriptions.

146. General economic principles recognize that any overcharge at a higher level of distribution generally results in higher prices at every level below. Moreover, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of Suboxone to Plaintiffs and members of the Class. The impairment and delay of generic competition at the direct purchaser level similarly injured end-payors who were equally denied the opportunity to purchase cheaper generic Suboxone equivalents.

147. During the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of Suboxone. As a result of Reckitt's illegal conduct as alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their Co-Formulated Buprenorphine/Naloxone requirements. Plaintiffs and the other Class members paid prices for Co-Formulated Buprenorphine/Naloxone that were

substantially greater than the prices that they would have paid absent the illegal conduct alleged herein.

148. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

**E. Effect on Interstate and Intrastate Commerce**

149. At all material times, Suboxone, manufactured and sold by Reckitt, was shipped across state lines and sold to customers located outside its state of manufacture.

150. During the relevant time period, in connection with the purchase and sale of Suboxone, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow of intrastate and interstate commerce.

151. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Reckitt, as alleged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

152. Reckitt's anticompetitive conduct occurred in part in trade and commerce within the states set forth herein, and also had substantial intrastate effects in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic Suboxone to end-payors inside each respective state. The foreclosure of generic Suboxone directly impacted and disrupted commerce for end-payors within each state, who were forced to pay supracompetitive prices.

**F. Monopoly Power**

153. At all relevant times, Reckitt had monopoly power over Co-Formulated Buprenorphine/Naloxone, because it had the power to raise and/or maintain the price of Co-Formulated Buprenorphine/Naloxone at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

154. To the extent that Plaintiffs are required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is all Co-Formulated Buprenorphine/Naloxone products—*i.e.*, Suboxone in all its forms and dosage strengths and the respective AB-rated generic bioequivalents.

155. A small but significant, non-transitory price increase by Reckitt to Suboxone would not have caused a significant loss of sales to other drugs or products used for the same purposes, with the exception of AB-rated generic versions of Suboxone.

156. At competitive prices, Suboxone does not exhibit significant, positive cross-elasticity of demand with respect to price, with any opioid dependence treatment or other product other than AB-rated generic versions of Suboxone.

157. Reckitt needed to control only Suboxone and its AB-rated generic equivalents, and no other products, in order to maintain the price of Suboxone profitably at supra-competitive prices. Only the market entry of a competing, AB-rated generic version of Suboxone would render Reckitt unable to profitably maintain supracompetitive prices for Suboxone.

158. Reckitt also sold branded Suboxone substantially in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

159. At all relevant times, Suboxone was unique and not reasonably interchangeable with other therapies for the treatment of opioid addiction. Suboxone was unique in that it is an

opioid replacement therapy (unlike Naltrexone). Suboxone was unique in that it is a maintenance therapy (unlike Subutex—Reckitt’s buprenorphine product not co-formulated with naloxone—which is recommended only for induction treatment, and is thus a complement to, not a substitute for, Suboxone). Suboxone was unique in that it was the only FDA-approved opioid replacement maintenance therapy (unlike methadone, which has never been formally approved by the FDA). Suboxone was unique in that it was the only opioid replacement maintenance therapy that was a Schedule III drug under the Controlled Substances Act and could be prescribed in an office setting under the Drug Addiction Treatment Act (DATA) of 2000 (unlike methadone, which is a Schedule II drug, and must be administered in a clinic setting). Suboxone was unique in that it was the only opioid replacement maintenance therapy that was co-formulated with an opioid antagonist (naloxone) to deter abuse. Suboxone was unique in that it was the only opioid replacement maintenance therapy that was only a partial (as opposed to full) agonist of the  $\mu$ -opioid receptor; thus, unlike methadone or other full agonists, Suboxone’s unique properties created a “ceiling effect” that prevented larger doses of buprenorphine from producing greater agonist effects, protecting patients against death by respiratory depression or overdose. This property also afforded Suboxone a unique efficacy profile: unlike methadone, which is prescribed for a patient population suffering from severe forms of opioid addiction, Suboxone was suitable only for patients with mild to moderate forms of opioid addiction.

160. The relevant geographic market is the United States and its territories.

161. At all relevant times, Reckitt enjoyed high barriers to entry with respect to the above-defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion.

162. Reckitt’s market share in the relevant market was 100% at all relevant times.

## **VII. CLAIMS FOR RELIEF**

### **CLAIM I**

#### **Monopolization And Monopolistic Scheme Under State Law**

163. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

164. At all relevant times, Reckitt possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Reckitt possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

165. Through the overarching anticompetitive scheme, as alleged extensively above, Reckitt willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby.

166. It was Reckitt's conscious objective to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

167. Reckitt's scheme harmed competition as alleged in detail above.

168. To the extent Reckitt is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Reckitt's actions comprising the anticompetitive scheme that outweigh the scheme's harmful effects. Even if there were some conceivable such justification that Reckitt were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

169. As a direct and proximate result of Reckitt's illegal and monopolistic conduct, as alleged herein, Plaintiffs and the Class were injured.

170. By engaging in the foregoing conduct, Reckitt has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

- a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Suboxone in Arizona by members of the Class.
- b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, and California common law with respect to purchases of Suboxone in California by members of the Class.
- c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Suboxone in the District of Columbia by members of the Class.
- d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Suboxone in Florida by members of the Class.
- e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Suboxone in Illinois by members of the Class.
- f. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Suboxone in Iowa by members of the Class.
- g. Kansas Stat. Ann. § 50-161 (b) *et seq.*, with respect to purchases of Suboxone in Kansas by members of the Class.
- h. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Suboxone in Massachusetts by members of the Class.
- i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Suboxone in Maine by members of the Class.
- j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Suboxone in Michigan by members of the Class.
- k. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota by members of the Class.
- l. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Suboxone in Mississippi by members of the Class.
- m. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Class.
- n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Suboxone in Nebraska by members of the Class.
- o. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Suboxone in Nevada by members of the Class.
- p. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases of Suboxone in New Hampshire by members of the Class.



- q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Suboxone in New Mexico by members of the Class.
- r. N.Y. Gen. Bus. Law §340 (“The Donnelly Act”), with respect to purchases of Suboxone in New Mexico by members of the Class
- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Suboxone in North Carolina by members of the Class.
- t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Suboxone in North Dakota by members of the Class.
- u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Suboxone in Oregon by members of the Class.
- v. 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of Suboxone in Puerto Rico by members of the Class.
- w. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases in Rhode Island by members of the Class.
- x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Suboxone in South Dakota by members of the Class.
- y. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases of Suboxone in Tennessee by members of the Class.
- z. Utah code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Suboxone in Utah by members of the Class.
- aa. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Suboxone in Vermont by members of the Class.
- bb. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Suboxone in West Virginia by members of the Class.
- cc. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Suboxone in Wisconsin by members of the Class.

## **CLAIM II**

### **Attempted Monopolization Under State Law**

171. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

172. Reckitt, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Reckitt's conscious objective to control prices and/or to exclude competition in the relevant market.

173. The natural, intended, and foreseeable consequence of Reckitt's overarching anticompetitive scheme was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

174. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Reckitt will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

175. As a direct and proximate result of Reckitt's illegal and monopolistic conduct, Plaintiffs and the Class were harmed as alleged in detail above.

176. By engaging in the foregoing conduct, Reckitt has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

- a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Suboxone in Arizona by members of the Class.
- b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, and California common law with respect to purchases of Suboxone in California by members of the Class.
- c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Suboxone in the District of Columbia by members of the Class.
- d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Suboxone in Florida by members of the Class.
- e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Suboxone in Illinois by members of the Class.
- f. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Suboxone in Iowa by members of the Class.
- g. Kansas Stat. Ann. §§ 50-161(b), *et seq.*, with respect to purchases of Suboxone in Kansas by members of the Class.

- h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Suboxone in Maine by members of the Class.
- i. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Suboxone in Massachusetts by members of the Class.
- j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Suboxone in Michigan by members of the Class.
- k. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota by members of the Class.
- l. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Suboxone in Mississippi by members of the Class.
- m. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchases of Suboxone in Missouri by members of the Class.
- n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Suboxone in Nebraska by members of the Class.
- o. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Suboxone in Nevada by members of the Class.
- p. N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Suboxone in New Hampshire by members of the Class.
- q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Suboxone in New Mexico by members of the Class.
- r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Suboxone in New York by members of the Class.
- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Suboxone in North Carolina by members of the Class.
- t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Suboxone in North Dakota by members of the Class.
- u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Suboxone in Oregon by members of the Class.
- v. 10 L.P.R.A. §§ 251, *et seq.*, with respect to purchases of Suboxone in Puerto Rico by members of the Class.
- w. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases in Rhode Island by members of the Class.

- x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Suboxone in South Dakota by members of the Class.
- y. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases of Suboxone in Tennessee by members of the Class.
- z. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Suboxone in Utah by members of the Class.
- aa. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Suboxone in Vermont by members of the Class.
- bb. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Suboxone in West Virginia by members of the Class.
- cc. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Suboxone in Wisconsin by members of the Class.

### **CLAIM III**

#### **Unfair And Deceptive Trade Practices Under State Law**

177. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

178. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and Class members were deprived of the opportunity to purchase a generic version of Suboxone and forced to pay higher prices for their Co-Formulated Buprenorphine/Naloxone requirements.

179. There was and is a gross disparity between the price that Plaintiffs and the Class members paid and for the brand Suboxone product and the value received, given that a much cheaper substitute generic product should have been available sooner and in greater quantity, and prices for brand Suboxone should have been much lower, but for Reckitt's unlawful conduct.

180. By engaging in the foregoing conduct, Reckitt has engaged in unfair competition or deceptive acts and practices in violation of the following state laws:

- a. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases of Suboxone in Arkansas by members of the Class.
- b. Ariz. Code §§ 44-1255, *et seq.*, with respect to purchases of Suboxone in Arizona by members of the Class.
- c. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases of Suboxone in California by members of the Class.
- d. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases of Suboxone in the District of Columbia.
- e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Suboxone in Florida by members of the Class.
- f. Kan. Stat. §§ 50-623, *et seq.*, with respect to the purchases of Suboxone in Kansas by members of the Class.
- g. Idaho Code §§ 48-601, *et seq.*, with respect to the purchases of Suboxone in Idaho by members of the Class.
- h. 815 ILCS §§ 505/1, *et seq.*, with respect to the purchases of Suboxone in Illinois by members of the Class.
- i. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to the purchases of Suboxone in Maine by members of the Class.
- j. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Suboxone in Massachusetts by members of the Class.
- k. Mich. Stat. §§ 445.901, *et seq.*, with respect to purchases of Suboxone in Michigan by members of the Class.
- l. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota by members of the Class.
- m. Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases of Suboxone in Missouri by members of the Class.
- n. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Suboxone in Nebraska by members of the Class.
- o. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of Suboxone in Nevada by members of the Class.

- p. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of Suboxone in New Hampshire by members of the Class.
- q. N.M. Stat. §§ 57-12-1, *et seq.*, with respect to purchases of Suboxone in New Mexico by members of the Class.
- r. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of Suboxone in New York by members of the Class.
- s. N.C. Gen. Stat. §§ 75-1.2, *et seq.*, with respect to purchases of Suboxone in North Carolina by members of the Class.
- t. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases of Suboxone in Oregon by members of the Class.
- u. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases of Suboxone in Pennsylvania by members of the Class.
- v. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Suboxone in Rhode Island by members of the Class.
- w. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases of Suboxone in South Dakota by members of the Class.
- x. Tenn. Code §§ 47-18-101, *et seq.*, with respect to purchases of Suboxone of Suboxone in Tennessee by members of the Class.
- y. Utah Code §§13-11-1, *et seq.*, with respect to purchases of Suboxone in Utah by member of the Class.
- z. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases of Suboxone in Virginia by members of the Class.
- aa. Vt. Stat Ann. 9, § 2453, *et seq.*, with respect to purchases of Suboxone in Vermont by member of the Class.
- bb. West Virginia Code §§ 46A-6-101, *et seq.*, with respect to purchases of Suboxone in West Virginia by members of the Class.

181. Plaintiffs and members of the proposed Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in detail above. Their injury consists of paying higher prices for Suboxone than they would have paid in the absence of these violations, and being denied the opportunity the purchase the cheaper generic Suboxone. These injuries are of the type the state consumer protection and unfair

business practices statutes were designed to prevent and directly result from Defendants' unlawful conduct.

**CLAIM IV**

**Injunctive And Declaratory Relief Under Section 16 Of The Clayton Act For Reckitt's Violations Of Section 2 Of The Sherman Act**

182. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

183. Plaintiffs' allegations described herein and in claims I through III comprise a violation of Section 2 of the Sherman Act, as well as state laws *supra*.

184. Plaintiffs and the members of the Class face an ongoing threat of injury for the Defendants' unlawful conduct, which is ongoing. Moreover, Plaintiffs and the members of the Class are threatened with injury, and are being injured, as result of prior unlawful conduct by the Defendants.

185. Plaintiffs and the members of the proposed Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201, hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Sections 2 of the Sherman Act.

186. Plaintiffs and the members of the proposed Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by Reckitt's unlawful conduct, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

**CLAIM V**

**Unjust Enrichment Under State Law  
(Fifty States & District of Columbia, Except Ohio and Indiana)**

187. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

188. Reckitt has benefited from monopoly profits on the sale of Suboxone resulting from the unlawful and inequitable acts alleged in this Complaint.

189. Reckitt's financial benefit resulting from its unlawful and inequitable acts is traceable to overpayments for Suboxone by Plaintiffs and members of the Class.

190. Plaintiffs and the Class have conferred upon Reckitt an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

191. It would be futile for Plaintiffs and the Class to seek a remedy from any party with whom they have privity of contract.

192. It would be futile for Plaintiffs and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Suboxone, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Reckitt.

193. The economic benefit of overcharges and monopoly profits derived by Reckitt through charging supracompetitive and artificially inflated prices for Suboxone is a direct and proximate result of Reckitt's unlawful practices.

194. The financial benefits derived by Reckitt rightfully belong to Plaintiffs and the Class, because Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Reckitt.

195. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Reckitt to be permitted to retain any of the overcharges for Suboxone derived



from Reckitt's unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

196. Reckitt is aware of and appreciates the benefits bestowed upon it by Plaintiffs and the Class.

197. Reckitt should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds it received.

198. A constructive trust should be imposed upon all unlawful or inequitable sums received by Reckitt traceable to Plaintiffs and the Class.

199. Plaintiffs and the Class have no adequate remedy at law.

### **VIII. DEMAND FOR JUDGMENT**

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Class, respectfully pray that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare Plaintiffs the representatives of the End Payor Class;

B. Enter joint and several judgments against Reckitt and in favor of Plaintiffs and the Class;

C. Declare the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;

D. Permanently enjoin Defendants pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 (a) and 26, from continuing their unlawful conduct, so as to assure that similar anticompetitive conduct does not continue to occur in the future;

E. Grant Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Reckitt's unjust enrichment

F. Award Plaintiffs damages as provided by law in an amount to be determined at trial;

G. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

H. Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

I. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by Reckitt's unlawful conduct, as the Court deems just.

#### **IX. JURY DEMAND**

200. Pursuant to Fed. R. Civ. P. 38, Plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury on all issues so triable.

Dated: August 15, 2013

Respectfully submitted:

**SPECTOR ROSEMAN KODROFF &  
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/s/ Jeffrey L. Kodroff (JLK 4986)

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